SERUM INSTITUTE OF INDIA PVT. LTD.
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Increasing GMP Compliance and Advantage of Outsourcing Non Core Activity to Professionals

Observations on Laundry:

- Garment washing /drying machine validation not performed

- Vendor approval process was found to be deficient. The new facility was built exclusively for the use of company. The contract in place did not prohibit laundry services, no exclusivity clause from entering into agreement with other manufacturers.

- The company validation for clean room garments washing and sterilization was found deficient. Defined tests to be conducted after the 25 Washing, Sterilization Cycle as well as the Helmke Drum test, Microbial Penetration tests, and the particle penetration test, air permeability and surface resistivity were no fully implemented.

Observations on Laundry:

- The requirements of *Annex 1 § 45* that clean area clothing should be cleaned and handled in such a way that it does not gather additional contaminants were not met for the in-house laundering of garments. For example:

a. The grade A/B garments were washed in potable water and dried in uncontrolled conditions.

b. There was no testing of the garments post cleaning to determine suitability for use.

c. The folding and packaging area was not classified or certified to any standard.

d. There was no formalized procedure or records for recording the actual number of garments received, washed, dried, packaged or rejected (including confirmation of disposal), and hence it could not be verified that specific load conditions were qualified.

Observations on Laundry:

- Unfiltered potable water and powder detergent is used. Purified water and liquid detergent is preferable.

- Folding done on stainless steel tables each under a small laminar flow hood. Replacement with illuminated inspection tables and improved laminar flow protection should be considered.

- The workers conducting inspection, folding and packing of uniforms wore clean room coats and either disposable hair nets or cotton caps, and hand gloves. However, this did not provide adequate protection from introducing particulate contamination. Face masks were not worn.

Observations on Laundry:

- Defined number of uses of clean room (body suit) garments (but not of head covering). However, recording of use of garment said to be done in production when garment to be disposed. This has risk of non-recording and recommended that this task be done as part of the laundry process.
- The folding of coveralls was done in a manner that did not facilitate easy use. The zips of the coveralls were closed and the coveralls were folded lengthways. Folding of the coveralls should be done so that the wearer can put on the coveralls with minimal contact of the external surfaces. This would include leaving the zip open and the folding being done in such a manner as to allow the wearer to minimize contact with the outside of the coverall and or the floor.
- It was not clear whether the test parameters selected by vendor were appropriate and whether the results obtained indicated ongoing suitability of the garments after 100 cycles.
- There was no effective means of recording the number of usage cycles of individual garments.

GUIDELINE REQUIRMENTS ON CLEAN AREA CLOTHING

Clean room area garments requirement as per Institute of Environmental Sciences and Technology (IEST):

- Cleanliness and cleanability
- Electrostatic properties
- Biological properties
- Durability
- Comfort
- Opacity
- Particle filtration efficiency
- Microbial penetration
- Chemical Compatibility
- Fluid resistance

Institute of Environmental Sciences and Technology (IEST):

As per IEST requirements, all processing of garments such as laundering, testing and initial packaging should be performed in cleanroom that meets the specified air cleanliness class in accordance with ISO 14644-1.

Institute of Environmental Sciences and Technology (IEST):

Testing:

- Water testing
- Particle penetration test
- Equivalent pore diameter test
- Releasable large particle test
- Particle dispersion test (Body box test)
- Helmke drum test
- Microbial penetration test

World Health Organization (WHO)

WHO TRS annex 6, Point no. 10.9:

Clothing used in clean areas should be laundered or cleaned in such a way that it does not gather additional particulate contaminants that Can later be shed. Separate laundry facilities for such clothing are desirable. If fibers are damaged by inappropriate cleaning or sterilization, there may be an increased risk of shedding particles. Washing and sterilization operations should follow standard operating procedures.

EU GMP

EU GMP guidelines, Point No.45 :

Clean area clothing should be cleaned and handled in such a way that it does not gather additional contaminants which can later be shed. These operations should follow written procedures. Separate laundry facilities for such clothing are desirable. Inappropriate treatment of clothing will damage fibers and may increase the risk of shedding of particles.

PIC/s Requirement

GMP guidelines Annex 1 Point No. 45:

Clean area clothing should be cleaned and handled in such a way that it does not gather additional contaminants which can later be shed. These operations should follow written procedures. Separate laundry facilities for such clothing are desirable. Inappropriate treatment of clothing will damage fibers and may increase the risk of shedding of particles.

OUTSOURCING ACTIVITY TO PROFESSIONALS

Use of Outsourcing:

- In case, in-house capacities are not sufficient or adequate
- In case, where the special techniques, area or equipments are required
- In case, in-house facilities are not equipped to carry out activities
- In case, expert guidance and support is required

THANK YOU